CHAPTER 7. PICTURE ARCHIVING AND COMMUNICATION SYSTEM (PACS) AND TELERADIOLOGY SYSTEMS

7-1. INTRODUCTION

a. The APPMO was chartered within the U.S. Army Medical Research and Materiel Command (USAMRMC) at Fort Detrick, Maryland, effective 19 March 2001. The APPMO is a corporate level coordination, execution and policy-making body that crosses functional elements of the AMEDD.

b. The creation of this Program Office reflects TSG direction to ensure the AMEDD PACS program is effectively managed and that PACS requirements are appropriately defined against the clinical need and supporting business case, prioritized and embedded throughout the AMEDD. A continuous assessment by this office will also identify improvement opportunities in support of AMEDD PACS initiatives.

c. The APPMO mission is to develop the Army's strategic vision for PACS and other medical imaging information systems as they evolve. The APPMO is responsible for executing the Army's PACS and teleradiology program to ensure successful and coherent planning, deployment, integration, sustainment and life cycle management to the Army's greatest clinical and financial benefits.

7-2. APPMO RESPONSIBILITIES

The APPMO is responsible for the following:

a. Conduct program and acquisition management to plan, organize, direct and control the proliferation and life cycle management of the AMEDD PACS and teleradiology systems.

b. Develop and sustain a business plan for AMEDD PACS with applicable consultants, the Army Medical Department Center and School (AMEDDC&S) and the USAMEDCOM. Build and manage the program objective memorandum (POM) for AMEDD PACS and teleradiology.

c. Continuously assess the state of fielded PACS systems within the AMEDD.

d. Manage pre-deployment, project management, implementation, and acceptance testing activities for newly procured PACS and major PACS upgrades.

e. Manage configuration control, ensure successful integration and interoperability, and champion life-cycle management of PACS by building integrated process team (IPT) partnerships with other AMEDD organizations.

f. Coordinate with AMEDDC&S and the USAMEDCOM to ensure PACS and teleradiology acquisitions are synchronized for TDA and TOE.

g. Coordinate with USAMEDCOM Assistant Chief of Staff for Installations, Environment, and Facility Management (ACSIE&FM), and Assistant Chief of Staff for

Information Management to identify site preparation and network augmentation requirements.

h. Coordinate with the Tri-service Infrastructure Management Program Office (TIMPO) to identify MTF network infrastructure requirements in support of PACS and teleradiology.

i. Work closely with the USAMMA to ensure PACS and PACS-related systems are included in the TARA processes.

j. Ensure that the AMEDD PACS vision and associated requirements are continually updated, integrated with other AMEDD and MHS, medical information systems and built into the acquisition process so that equipment to be fielded can be operated, maintained, and supported efficiently and effectively.

k. Ensure that necessary policy, plans and controls are in place and updated when required, and that appropriate organizations are capable of executing PACS initiatives in a manner consistent with the clinical business practices defined by the TSG Radiology Consultant and Regional Radiology leadership.

7-3. PROGRAMMING AND FUNDING

a. Each year the APPMO refines the PACS/teleradiology strategic plan and out-year budget estimate. The TSG Radiology Consultant will review and offer advice toward this final plan/requirement.

b. The APPMO prepares a briefing of the finalized plan for presentation to the STCPC. The STCPC reviews the plan and recommends the appropriate level of OP and OM funding for PACS and teleradiology in the next FY's program. APPMO participates in senior executive briefings as necessary to support the STCPC approval process, or if requested by the Deputy Surgeon General (DSG) or TSG, APPMO briefs the senior executives on the status of the program and related funding levels. The consultant should be a part of this briefing team or available to the brief as necessary to demonstrate functional Radiology Consultant and programmatic concurrence to the decision makers.

c. Once senior executives grant approval, USAMEDCOM provides funding to the APPMO for the program.

(1) MEDCASE-funded requirements are prepared by the APPMO and entered into the WebMRE system by the USAMMA. The USAMMA forwards the requirements to the TSG Radiology Consultant via transmittal. The APPMO obtains document numbers from sites targeted in the funded plan and the USAMMA submits requisitions to DSCP.

(2) For OM-funded requirements APPMO will prepare and forward funding for procurement to DSCP. The APPMO will obtain document numbers from individual sites.

d. APPMO coordinates clinical/network assessment site visits as necessary with the regions and provides the opportunity to the radiology consultant to discuss enterprise business processes with the applicable regional radiology chair.

e. The regional radiology consultant reviews their respective regional radiology business strategy and reaches consensus with the APPMO on the capability which can be achieved with available funding. This plan serves as the baseline requirement for all system acquisitions within the region.

f. The APPMO works with DSCP, or other contracting agencies as appropriate, to negotiate best lifecycle pricing and ultimately reach contract award with the most appropriate vendors, monitors contract execution, and fields and accepts the systems.

7-4. PLANNING AND ASSESSMENTS

a. Planning and assessments are a continuous process that begins long before funds are obtained by the APPMO from the USAMEDCOM.

b. PACS are medical systems that traverse an MTF's enterprise both clinically and physically. In some larger sites, these complex systems are composed of hundreds of devices that must be placed on the site's property book. Establishing a site cross-functional project team to organize and focus the efforts onsite is essential to the successful implementation and/or modernization of a PACS in a facility. The site project team consists of key stakeholders, often including representation from senior management, radiology, information management, logistics (e.g., medical maintenance, property book officer, etc.), facilities management, nursing, and referring physicians. The team assists in all aspects of system rollout, including planning, implementation, government testing, and training. In addition, establishing a medical center or RMC-level executive project team prior to a new installation or a major system upgrade has proven to be an effective tool in facilitating the project planning process.

c. When a site initially implements PACS, identifying the site PACS system administrator (SA) early in the planning process is essential. Ideally, there is a PACS SA from radiology to administer the day-to-day clinical operations of PACS throughout the enterprise, and a PACS SA from information management to administer the PACS servers and related internal and external telecommunications. To ensure efficient operations of the PACS, the local command must allow sufficient time for each SA to perform their daily duties. The amount of time required for radiology and the Information Management Division (IMD) PACS' SAs depends on the size of the MTF, the inventory of PACS devices installed, and the extent of compliance by the end users to the local digital imaging policy and procedures.

d. The APPMO assigns a project manager to advise the region and sites in getting organized into project teams of the proper functional types, and preparing for the clinical and network assessments to follow.

e. Initial site visits are conducted by the APPMO as part of the planning phase to educate as well as to gain a greater understanding of the environment and requirement. These site visits focus on the following two areas:

(1) The clinical assessment focuses on analyzing the workflow and identifying clinical requirements (e.g., quantity, proposed locations, and types of PACS workstations, specific imaging modalities and their locations, and assessing the

current print backup capability). This assessment is performed by the clinical component of the APPMO office, the APPMO network engineer, and the appropriate site project team personnel.

(2) The network assessment focuses on the data transfer aspects of either installing a new system, or modernizing an existing system. Areas assessed are the capacity of the current network infrastructure to support the proposed PACS components in the required locations; existing cabling and if any additional cabling is required; existing uninterruptible power supply (UPS) capacity, emergency generator power capability, and physical space in the data center for the core PACS hardware. The team also documents existing networking hardware, performs an assessment of network security, and documents the existing capacity of all pertinent wide area network connections. The network assessment is performed by the network engineering component of the APPMO, and the appropriate site project team personnel.

f. The clinical/network assessment results in a detailed report that includes or identifies the following:

(1) A list of existing equipment to be integrated, including locations and status

(2) Proposed locations for new equipment

(3) Identification of workflow issues or problems that may benefit by the implementation of PACS (or possibly re-engineer one or more workflow issues for more efficient operations)

(4) Critical networking, security, or bandwidth issues that should be addressed with recommendations for resolution

(5) Any high-level site preparation or cabling required for the project.

7-5. SITE/REGIONAL PROJECT TEAM ACTIVITIES — ASSESSMENTS AND IMPLEMENTATIONS

a. For each site survey and implementation a site project team consisting of the APPMO regional project manager, the RMC project manager, site project manager, and site participation from the diagnostic imaging, IMD, medical maintenance, logistics, and facilities sections is essential for the smooth and efficient implementation of PACS. The project team is responsible for the following tasks:

(1) Identifying all imaging modalities and printers to be integrated into the PACS.

(2) Identifying the number, type and location of workstations to be installed or upgraded, as balanced against available funding. What is minimally required?

(3) Reviewing alternative timelines for implementation and training, and ensuring that timelines for installations/upgrades do not interfere with MTF clinical operations.

(4) Identifying and developing an approach for information assurance documentation, required facility renovations, and training schedules.

b. Typically the USAMEDCOM and the TIMPO are responsible for all network infrastructures at MTFs in support of PACS and teleradiology. However, when the PACS network assessment is conducted, if there are significant PACS-focused networking and security issues that cannot be resolved quickly through the USAMEDCOM, the APPMO seeks additional funding to augment the infrastructure for optimum performance of PACS. This may be done at the expense of the regional PACS budget, so all efforts are made to have the USAMEDCOM appropriately support this area through their Information Management/Information Technology (IM/IT) budgets.

c. Site preparation requirements for PACS implementation are jointly developed by the site and the APPMO clinical survey team. While the APPMO can help identify the requirements, the site is ultimately responsible for programming/ requesting site preparation funds.

d. Specific requirements

(1) Computer room/data center — many computer rooms do not have adequate space for the placement of PACS storage devices and associated PACS equipment.

(2) Radiologist viewing/reading rooms — inadequate viewing areas; transitioning from film viewing to soft-copy displays require physical changes to the viewing environment (i.e., heating, ventilation, and air-conditioning, UPS, ambient light reduction, light diffusers, anti-reflective surfaces, and anti-reflective paint for walls).

e. The APPMO with the USAMMA identifies requirements for modality integration — seamless modality integration using standard DICOM protocols. The cost of upgrading modalities to provide the minimum-required DICOM functionality for interoperability is borne by the MTF/region as an operating expense, unless the upgrade qualifies for MEDCASE funding.

f. A CHCS interface is required to promulgate patient demographic information to the PACS. The CHCS interface is currently unidirectional; however future requirements call for a bidirectional interface.

7-6. VENDOR SELECTION

a. For large new system procurements or major modernization projects the APPMO, in conjunction with the regional project team, develops a RFP on a regional basis. The intent is to optimize sustainment and minimize cost through regional standardization of PACS configurations. The request for information/request for proposal (RFI/RFP) clearly defines regional PACS requirements within the system lifecycle (presently 8 years) and “locks in” acquisition and sustainment costs for that region over the 8-year period.

b. The APPMO, with participation and assistance by the regional project team, selects a vendor for the region. Vendor selection is based on clinical preference and overall cost of ownership for the life of the product.

(1) The APPMO project manager and selected APPMO staff, along with selected members of the regional project team, comprise the evaluation panel. The evaluation panel reviews the vendor technical proposals and evaluates clinical fit, past performance, lifecycle cost, and delivery. The panel summarizes their findings and renders a recommendation of the optimal solution to the APPMO project manager.

(2) The APPMO project manager considers the recommendation of the evaluation panel and may either approve as is or request further due diligence and supporting rationale for the vendor selection. The APPMO project manager makes the final award decision. If the site disagrees with the selection, the Principal Assistant for Acquisition, USAMRMC, is the final authority for award.

c. After a vendor has been selected, the APPMO works with the DSCP to issue a delivery order against the DIN-PACS II contract.

d. For smaller system procurements such as the addition of a hub or spoke teleradiology node to an existing teleradiology system, or minor site level upgrades or enhancements to existing systems (typically valued at less than $500,000), the APPMO works directly with the regional project team to fine tune the requirement and negotiates with vendors to get best pricing before requesting DSCP (or other contracting agencies) to cut contracts for equipment.

7-7. ACCEPTANCE TESTING

a. The USAMMA is responsible for managing the acceptance test program for PACS throughout the AMEDD and has matrixed personnel within the APPMO for this purpose. Final acceptance of the installation is made by DSCP based on the results of acceptance testing, which is coordinated through APPMO as the central decision authority for PACS and teleradiology programs.

b. System acceptance inspection testing shall include complete inspection and verification of functional operation of the DIN-PACS, including all ancillary components and turnkey installation. The acceptance test verifies that the system and the turnkey installation comply with the DIN-PACS II contract requirements as well as the contractor's published specifications. If the contractor's specifications furnished with his technical proposal exceed the Government's requirements, the Government tests and accepts the system on the contractor's specifications. In all other cases, in the event of any other conflict between the contractor's published literature and the requirements of the specification, the requirements of the specification shall take precedence. Noncompliance with any specified requirements or presence of one or more defects may constitute cause for rejection.

c. On completion of installation of all equipment and systems software comprising the system as defined in the site specific delivery order (and turnkey installation), the contractor furnishes a written notice of readiness for inspection of the system (and turnkey installation) to DSCP. With this notice, the contractor certifies in writing that:

(1) The particular system is installed
(2) The system is ready for acceptance testing
(3) The system complies with the manufacturer's specifications AND with all the requirements of the DIN-PACS II contract specification

d. The contractor makes its best effort to provide an estimate of expected date of readiness to DSCP roughly 2 to 3 weeks in advance (the contractor will not be bound by this estimate) to allow both the government and contractor additional time to plan personnel schedules.

e. The acceptance inspection test shall be conducted only on a complete, integrated system. The acceptance inspection test consists of a series of validation steps for each requirement in the DIN-PACS II contract and includes tests to validate both component performance and system integration performance.

(1) Testing is conducted in accordance with the most current version of the government's clinical use determination/acceptance testing (CUD/AT) protocol available at the time of acceptance testing.

(2) The Government first conducts a basic level of testing as defined in the CUD/AT protocol to make a CUD. The CUD/AT inspection will normally be conducted during a single, continuous testing period. The vendor is responsible for connecting test equipment and operating the system during inspection testing. Minor discrepancies that may be corrected during the inspection shall not be cause for rejection.

(3) If acceptance inspection testing has not commenced within 30 calendar days from date of receipt of the contractor's notice of readiness for inspection, the government shall accept the system, and subsequently set final acceptance of the system as the date of notice of readiness for inspection.

(4) If the system is rejected as a result of the CUD/AT inspection, the contractor shall be advised via letter from DSCP as to deficiencies which were cause for rejection. It is the contractor's responsibility to correct reported deficiencies and advise DSCP in writing when all corrections have been made and equipment is ready for re-inspection. Re-inspection shall be performed by the Government with all costs incurred chargeable to the PACS vendor.

(5) If deficiencies found at the time of CUD/AT inspection are corrected within 30 calendar days after receipt of the deficiency letter from the contracting officer, final acceptance will be issued on validation of deficiency correction by the government, and the start date for the warranty shall be backdated to the date of CUD.

f. Other systems or equipment items purchased with the PACS, and not covered under the DIN-PACS II CUD/AT protocol may also be tested during the system acceptance test. Systems will be tested per the manufacturer's protocols for commercial testing unless an appropriate government testing protocol is available.

7-8. SUSTAINMENT

a. The APPMO is the corporate champion for the PACS maintenance and sustainment IPT. The team has a multi-functional mix of clinical, medical maintenance, IM/IT, and project management personnel with a primary focus on the product as it supports the medical mission, and the overall costs of its sustainment. The IPT is responsible for recommending ways to minimize the sustainment costs for

PACS while at the same time balancing cost reductions with maximizing the clinical availability of this mission-critical medical system.

b. The approach of the IPT includes the following:

(1) Define the requirements for maintenance by identifying maintenance intensive items

(2) Measure/assess operational and clinical availability in terms of up-time performance

(3) Analyze the derived benefit gained through contracted service programs

(4) Improve/increase maintenance efficacy through training and modified service contracts

(5) Control the maintenance program by continuously evaluating organizational needs – clinical and operational

c. With the emergence of new technologies, such as PACS and teleradiology, comes the requirement for identifying ownership and management of these medical systems. Medical device tracking and management is paramount to successful Joint Commission on Accreditation of Healthcare Organization (JCAHO) inspections. However, many AMEDD MTFs erroneously consider these systems to be IT systems which do not require the same level of accountability and management as medical devices. This places the AMEDD at risk, due to lack of historical documentation and understanding. All Food and Drug Administration (FDA)-approved medical devices and systems/subsystems must be listed in the site's property book, and all maintenance and changes to the product tracked in the appropriate device history record.

d. In addition to the asset management requirements to support these systems, facilities must recognize that local support resources must be trained and made available across a number of functional areas within each facility to realize the clinical efficiencies associated with these systems. The functional areas impacted most heavily by the installation of PACS are the following:

(1) Radiology department. Provides clinical systems administration support.

(2) IM/IT department. Provides technical systems support for distributed devices, networks, and core PACS equipment located within the facility data center and protects all medical devices from attack or non-vendor modification through the use of firewalls and network security policies. Details of how the corporate IM/IT community will conduct its efforts and the policies to protect all medical devices are still being considered at the time of the writing of this publication. Questions concerning information assurance and network security should be addressed to the local, regional, and corporate chief information officer for the latest policies and procedures.

(3) Logistics/clinical engineering division. The Property Accountability Branch manages device history records and performs scheduled and unscheduled services on distributed medical devices/systems, as well as managing service

contracts on the systems. Whether medical maintenance or IM/IT provides support for medical workstations is still being decided at the time of the writing of this publication. Monitor calibration falls under the medical maintenance purview, and networking falls under IM/IT. Most likely, the vendor will maintain the clinical application software for workstations and servers.

7-9. PROPERTY ACCOUNTABILITY AND MAINTENANCE MANAGEMENT OF DIN-PACS

a. USAMEDCOM maintenance activities ensure the DIN-PACS system and all components are properly accounted for in the DMLSS. Device tracking is a requirement of JCAHO. Appendix A contains detailed procedures.

b. Documentation of scheduled and unscheduled maintenance within the maintenance module of DMLSS is key for proper accountability and provides data necessary to categorize cost drivers and identify tasks performed as part of a comprehensive government program to reduce costs associated with DIN-PACS. Accurate property accountability also assists activities when making corporate decisions regarding requisite skills or training to sustain DIN-PACS.

c. Each year, the APPMO requests maintenance quotes for all regions from the PACS vendors. These quotes are used by the APPMO to develop the PACS and teleradiology maintenance funding requirements for the next fiscal year. The APPMO provides these funding requirements, by region, to the USAMEDCOM who, in turn, provides fenced dollars in each MTF's resource summary for PACS and teleradiology maintenance. On or about 1 October of each year, the maintenance chief at the MTF and/or region should forward a funded requisition to DSCP for the next year's maintenance service contract citing the fenced dollars in the resource summary for that fiscal year. DSCP then issues annual service contracts for the period 1 October to 30 September of the given year. Medical maintenance at each MTF is responsible for tracking performance against the contract and notifying the APPMO and DSCP of any breaches of uptime requirements or performance issues related to the annual service contract.

7-10. TELERADIOLOGY FUNCTIONALITY

a. Teleradiology is essentially distributed radiology and a means of electronically transmitting radiographic patient images and consultative text from one location to another. The original purpose of this capability was to provide primary interpretation capability for radiology exams acquired at MTFs without assigned radiologists and to provide additional radiologist support for those sites that are understaffed on a temporary or permanent basis. Current planning includes the exporting of radiological exams to remote sites for interpretation by underused radiologists, expanding the options for achieving maximum use of radiology personnel resources. For the purpose of image acquisition, specially configured teleradiology equipment may be used for this function or the same equipment at primary PACS sites may be used. The concept allows for central-reading MTFs (hubs) staffed by radiologists to read digital images transmitted via communications links from satellite MTFs, or when radiologists are deployed and the operations tempo is slow, transmitting home site workload to them on a global basis to keep their skills up and continue to provide support to their home MTFs.

b. Either commercial or government-provided communications links can be used for teleradiology as long as they are secure and available for clinical use. Sites can use a variety of secure communications links including dedicated terrestrial or satellite-based T-1, Integrated Services Digital Network circuits, fractional T-1 (dial-up switched-56K service), digital subscriber line (DSL), asymmetric digital subscriber line (ADSL), or cable modems where available. World-wide electronic

transmission, using lossless data compression and encryption, can be real time or scheduled for after normal working hours as needed to help get better utilization of limited communications circuits. The transmission method chosen and the bandwidth of the transmission path affect the throughput from the hub to the spoke. This must be understood in the planning of the teleradiology operational concept. Factors such as image size, volume, and acceptable turnaround time will help determine the bandwidth requirement of communications links chosen for support of teleradiology. Full bit depth of the original acquired image data set will be transmitted to permit full diagnostic capability at the receiving site. Thus, while transmission compression is permitted, it must be bit preserving (lossless) and fully reversible. Transmission of teleradiology images must be able to be performed in both real time and scheduled batch mode. Unattended batch-mode transmission would normally be used for routine clinical workload, and real-time immediate mode would be used to support the fast turnaround time requirements of emergency medicine. Teleradiology projects are already implemented in Europe, Korea, the Pacific Basin, Southwest Asia, the Balkans, Alaska, and the RMCs in CONUS. These projects use various Army and Air Force MTFs as the hubs.

c. An additional goal of the APPMO is to provide at-home, secure teleradiology capability, extending the radiologists' office into their home when they are on call. This will be accomplished using a locally-procured (government-furnished) PC-based workstation that is either transportable to the physician's home or via a modular upgrade that can be applied to an existing home PC. The at-home PC would typically receive radiological exams via a high-speed commercial internet service provider using DSL, ADSL, or cable modem communications technology. The radiologist would report findings back to the hospital CHCS directly or by an e-mail type program.

7-11. INFORMATION ASSURANCE

a. As the program management organization responsible for the acquisition and fielding of Radiology PACS for the Army, the APPMO has been tasked with developing an effective information assurance program for PACS and teleradiology systems. A key component of this program is the institution of new processes to report and respond to information assurance vulnerability alerts (IAVAs), as well as other threats to Army healthcare systems. Because most information assets covered under this program are classified as medical devices, and are, therefore, subject to regulation by the FDA, full participation and support by industry and the clinical users is required for the successful execution of the Army's radiology mission.

b. The Commanding General, USAMRMC, has been assigned as the designated approving authority for information assurance and security for centrally deployed PACS and teleradiology systems. The APPMO is working with the OTSG, USAMEDCOM, Information Systems Engineering Command, and MHS to help design and implement defense-in-depth, protected-enclave, network segment architectures to protect vulnerable FDA-approved medical devices and systems.

c. The APPMO is assisting in the coordination and compliance with PACS and related devices used for digital imaging in the Army MTF environment. With the recent commitment to security improvements and compliance on PACS and related devices, the APPMO acts as a liaison for incorporating these needs into improved processes. This allows the Army healthcare system to continue to provide mission critical patient care needs in a responsive and secure way.

d. As of the date of this SB, the following systems have completed the Defense Information Technology Security Certification and Accreditation Process (DITSCAP) and have a signed authority to operate (ATO):

The **Agfa Impax Version 4.5**
The **MedWeb Distributed Teleradiology Version 4.5**
The **General Electric Centricity 2.0**
The **Fuji Synapse Version 3.0**

The Agfa Impax Version 6.0 and General Electric Centricity 3.0 are pending and should be completed within the next few months. Other systems continue to be evaluated on a case-by-case basis. The new DOD Information Assurance Certification and Accreditation Process (DIACAP) is being evaluated and, at this time, it is unclear whether systems in the future will be centrally, regionally, or locally accredited. The required IAVAs and the USAMEDCOM guidance directives have not yet addressed the FDA issues for medical devices, which require vendor authorization prior to installing and applying any necessary patches, updates, or changes to these medical systems.

e. The APPMO mission is to provide PACS technology to all MTFs across the AMEDD by FY 2007. As sites are completed, their POC will be added to the APPMO list for correspondence. The APPMO, with assistance from the USAMMA, will complete and maintain a database of all the PACS and related medical devices, along with vendor contact information and status of compliance. This inventory is essential for ensuring compliance with all PACS equipment across the AMEDD.

f. The APPMO Information Assurance Manager is the central POC for PACS vendors and works with the Regional Information Assurance Managers and/or facility information assurance managers or designated POCs to facilitate vendor-product-site IAVA issue resolutions. The APPMO advises the regions on the status of updates and monitors vendor compliance schedules to encourage them to resolve IAVA non-compliance issues as quickly as possible. Regions will request extensions or waivers or both as necessary and the APPMO will also keep the USAMEDCOM information assurance program manager apprised of all security related issues with respect to IAVA and PACS/teleradiology security matters.